

REMARKS

Applicants intend this response to be a complete response to the Examiner's **22 March 2005 Non-Final Office Action**. Applicants have numbered the paragraphs in their response to correspond to the paragraph numbering in the Office Action for the convenience of the Examiner. Please note that related paragraphs are combined in paragraph number ranges, *e.g.*, 2-3.

General Remarks

The present invention is not obvious over any of the cited reference taken alone or any combination.

Eggert et al.

Applicants are still completely perplexed by the Examiner's continued misplaced reliance on Eggert et al. The Examiner relies on Eggert et al to support pulse simulation. However, Eggert et al use the word "pulse" only eight time in the entire specification. Col. 1, l. 18, Col. 4, l. 65, Col. 5, l. 11, Col. 6, l. 27, Col. 12, l. 9, Claim 2, and twice in Claim 14. Of these eight instances, one refers to "systolic and diastolic pulse," which is specific to blood pressure and has nothing to do with an arterial pulse (Col. 1, l. 18); one refers to "a 77 year old pulseless female victim scenario" (Col. 12, l. 9). In all other occurrences, the word pulse is associated with the word oximeter -- a pulse oximeter is a monitor for measuring blood oxygentation. None of the pulse references in Eggert et al relate to an arterial pulse such as the one felt in a patient's wrist or neck.

Eggert et al. simply does not disclose, teach or suggest a device capable of simulating an arterial pulse such as the one felt in a patient's wrist. Eggert et al. does disclose tactile switches, but they are ON/OFF switches used to ensure proper placement of a pulse oximeter (an oxygen sensor for measuring hemoglobin carrying blood) on the finger of the manikin and a blood pressure device on the arm of the manikin. *These switches*, the cuff and the blood pressure swithces, *are incapable of generating touch discernible arterial pulses* such as one would feel in a patient's wrist. The tactile switches of Eggert et al. simply complete a circuit as does a light switch; the only difference being that one requires a toggle motion to turn on

and off, while the other requires a pressure to turn on and off. But they are not devices for simulating a pulse such as a the pulse one would feel in a patient's wrist. Because Eggert et al. makes absolutely no reference to a pulse generator, a person of ordinary skill in the art would not rely on Eggert et al. to teach or even suggest or motivate one to design a system including a pulse simulation. Moreover, because Eggert et al. lacks a suggestion of pulse simulation, Eggert et al. is not capable of being combined with the other reference relied on by the Examiner. Although a prior art device "may be capable of being modified to run the way [the patent applicant's] apparatus is claimed, there must be a suggestion or motivation in the reference to do so." In re Mill, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Claim Rejections - 35 USC § 103

3. **Claims 1, 2 and 8-27** stand rejected under 35 U.S.C. 103(a) as being unpatentable over Eggert et al (US 5853292) in view of Lampotang et al (US 5769641) and Tjølsen et al. (US 6007342). Applicant traverses this rejection and requests reconsideration in light of the claim amendments, if any, and the remarks set forth below.

With respect to independent claims 1, 2, 20 and 25, Applicant acknowledges that Eggert et al. generate sounds, particularly heart beat sounds. However, Applicant disagrees that Eggert et al disclose in any way pulse generators for simulating an arterial pulse such as the pulse felt in a patient's wrist. Eggert et al disclose no sensors at any position to generate a feelable pulse. Eggert et al do not disclose, teach or even suggest a device to generate a tactile output simulating an arterial pulse designed to be detected by touch.

The Examiner cannot rely on the tactile switches of Eggert et al to support pulse simulation – the Eggert et al switches are designed to ensure proper attachment of the pulse oximeter cuffs **18d** and blood pressure cuff **18e** to the manikin and **are incapable of generating pulses designed to simulate an arterial pulse.**

FIGS. 5a-5d illustrate details of the **BP cuff 18d** and the **pulse oximeter finger cuff 18e**. The cuffs **18d, 18e** are configured together wherein a cable **86** is provided that connects to the BP/OSAT/HEARTRATE port **48** and bifurcates into the respective cuffs. Electrical leads **86a** and **86b** connected to the respective cuffs **18d** and **18e** are depicted at one end of the cable **86** in FIG. 5b for connection to the EKG port **48** (FIG. 3). As shown in FIGS. 5c-5d with

respect to the finger cuff **18e**, a tactile switch **88** connected to a line **90** of the cable **86** is mounted in the finger cuff and is activated to complete a circuit when the cuff is secured properly with velcro (male) **91a** and velcro (female) **91b** to the finger of the manikin **28**. Similar switch circuitry, though not shown, is contained in the BP cuff **18d**.

Eggert et al. at Col. 6, ll. 26-40 (emphasis added). Applicant is absolutely perplexed by the Examiner continued assertions that Eggert et al. teach a tactile device which allows a person to feel an arterial pulse. The cuffs of Eggert et al. are associated with a pulse oximeter device and a blood pressure device. A pulse oximeter device is defined as follows:

Pulse oximetry is a simple non-invasive method of monitoring the percentage of haemoglobin (Hb) which is saturated with oxygen. The pulse oximeter consists of a probe attached to the patient's finger or ear lobe which is linked to a computerised unit. The unit displays the percentage of Hb saturated with oxygen together with an audible signal for each pulse beat, a calculated heart rate and in some models, a graphical display of the blood flow past the probe. Audible alarms which can be programmed by the user are provided. An oximeter detects hypoxia before the patient becomes clinically cyanosed.

See http://www.nda.ox.ac.uk/wfsa/html/u05/u05_003.htm.

The switches of Eggert et al. are designed solely to complete a circuit and are utterly incapable of generating touch discernable simulated arterial pulse. **The only purpose the tactile switches of Eggert et al. serve is to ensure that the student can properly attach a pulse oximeter to the finger of a patient and to properly attach a blood pressure device to a patient.** The Examiner's position on this matter is simply unsupported by the disclosure of Eggert et al. As stated previously, Eggert et al uses the word "pulse" only eight time in the entire specification and never in associated with generating a simulated arterial pulse.

Eggert et al. simply does not disclose, teach or suggest an apparatus including a tactile response system for generating a touch discernable arterial pulse and an audio response system for reproducing heart sounds in a correlated manner. Without a suggest in Eggert et al, the Examiner is not entitled to combine this reference with any other reference. Although a prior art device "may be capable of being modified to run the way [the patent applicant's] apparatus is claimed, there must be a suggestion or motivation in the reference to do so." In

re Mill, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Therefore, Applicant wholly rejects that Examiner's combination of Eggert et al with Lampotang et al and Tjølsen et al.

Although Applicant utterly rejects the Examiner's reliance of Eggert et al and its combination with any reference that suggests an arterial pulse generator, Applicant will address the combination below. However, Applicant must clearly point out that Eggert is unquestionably void of any suggest of arterial pulse generation and therefore is impermissibly combined with the other references.

Lampotang et al. do nothing to eliminate the basic deficiencies of Eggert et al. While Lampotang et al. relates to a simulator for simulating human responses during medical procedures, the manikin is capable of generating lung sounds, heart sounds and radial pulses (even though the specification gives no explanation of how the pulses are generated or how they are perceived), but Lampotang et al do not disclose, teach or suggest that the radial pulse be synchronized with heart sounds, a key feature of the present invention – "normal and abnormal breath sounds are synchronized with the bellows movement." Lampotang et al. at Col. 12, ll. 38-40. The present invention is designed to train healthcare providers in how to diagnosis heart and respiratory problems using only touch and a stethoscope:

As far as Applicant's attorney can determine, the Lampotang et al. manikin does not include any tactile output devices. Applicant's attorney searched the patent extensively for every conceivable verbal description of such a device and found none.

Moreover, Lampotang et al. do not disclose, teach or suggest ensuring that the heart sounds and pulses going to the EKG are correlated. Clearly, the pulse network is synchronize so that pulse propagation profiles can be simulated in the device. However, this pulse simulation system does not produce a signal detectable by touch – no tactile devices.

Therefore, a combined Eggert et al. and Lampotang et al. device would have no mechanism of outputting a touch discernible pulse simulation correlated to heart sounds, because neither reference includes a device that a student can touch and discern a pulse. Thus, the combined device fails to include or suggest a touch output device or correlating touch and sound, the two key ingredients in a device of this invention designed

to train medical students in the proper use of a stethoscope and touch as a front line diagnostic.

Next, the Examiner attempts to rehabilitate Eggert et al and Lampotang et al. with Tjølsten et al. Although, Tjølsten et al. do include a pulse simulator, there is no mention in Tjølsten et al. to correlate the pulse with heart sounds discernible with a stethoscope. Thus, the combination of Eggert et al, Lampotang et al and Tjølsten et al, if combinable, which Applicant believes is unsupportable, does not give rise to the present invention, because there is no suggestion in any of the patents to correlated the heart sounds and the pulses so that a healthcare provider can be trained in the proper use of a stethoscope and touch to diagnosis heart and respiratory abnormalities.

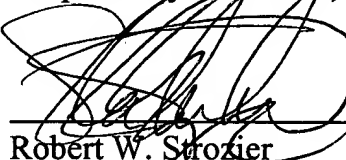
Because neither Eggert et al., Lampotang et al., Tjølsten et al. nor their combination disclose, teach or suggest a device including a tactile sensory output device (touch discernible), especially one correlated to heart sounds, the present invention is therefore clearly not obvious for Eggert et al in view of Lampotang et al further in view of Tjølsten et al. Applicant, therefore, respectfully requests withdrawal of this section 103(a) rejection.

As to all other claims, which depend from on of the independent claims 1, 2, 20 or 25, these claims are patentably distinct over the combination of Eggert et al., Lampotang et al., Tjølsten et al. because they depend from these independent claims and the independent claims are fully distinguished over the combination of Eggert et al., Lampotang et al., Tjølsten et al. as set forth above.

If it would be of assistance in resolving any issues in this application, the Examiner is kindly invited to contact applicant's attorney Robert W. Strozier at 713.977.7000

Date: August 9, 2005

Respectfully submitted,



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